UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 6, 1999

MEMORANDUM:

Subject: EPA Reg. No.: 211-25/ PHENO-CEN
DP Barcode: D250161
Case No.: 2045

EPA Reg. No. 211-36/ TRI-CEN GERMICICDAL DETERGENT
DP Barcode: D250170
Case No. 2045

From: Ann Hanger, Environmental Protection Specialist A. Hanger
Product Reregistration Branch
Special Review and Reregistration Division (7508C) MJP

To: Barbara Briscoe, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Central Solutions, Inc.
3130 Brinkerhoff Road
P.O. Box 15276
Kansas City, Kansas 66115

FORMULATION FROM EPA Reg. No. 211-25 LABEL:

	% by wt.
Active Ingredient(s):	
Potassium ortho-benzyl-para-chlorophenate.....	8.03%
Potassium ortho-phenylphenate.....	6.28%
Potassium para-tertiary-amylphenate.....	4.30%
Inert Ingredient(s):	81.39%
Total	100.00%

FORMULATION FROM EPA Reg. No. 211-36 LABEL:

	% by wt.
Active Ingredient(s):	
Sodium ortho-benzyl-para-chlorophenate.....	4.40%
Sodium ortho-phenylphenate.....	2.82%
Sodium para-tertiary-amylphenate.....	2.49%
Inert Ingredient(s):	90.29%
Total	100.00%

BACKGROUND: In the 8 month response to the Ortho-benzyl-p-chlorophenol (OBPC) RED, the registrant submitted acute toxicity studies to support the reregistration of their product, EPA Reg. No. 211-25. In addition, the registrant has cited the acute toxicity studies for EPA Reg. No. 211-25 to support the reregistration of EPA Reg. No. 211-36. Both products are not addressed by the OBPC RED. The MRID's are as follows: 446504-01, 443320-06, 443320-08, 443320-07, 446504-02, and 443320-09. The acute oral study (81-1) was conducted by Hill Top Biolabs, Inc. The remaining studies were conducted by MB Research Laboratories, Inc. The test material used in the studies was EPA Reg. No. 211-25.

RECOMMENDATIONS:

- The request for EPA Reg. No. 211-36 to cite the data for EPA Reg. No. 211-25 is acceptable.
- The acute oral (81-1), acute dermal (81-2), and acute inhalation (81-3) studies are acceptable.
- The primary eye irritation (81-4) and primary dermal irritation (81-5) studies indicated that EPA Reg. No. 211-25 is corrosive. A category I will be assigned for both 81-4 and 81-5 due to corrosive nature of the product (pH greater than 11.5).
- Due to the category I placement for primary dermal irritation an abbreviated review of the skin sensitization study was performed since Personal Protective Equipment (PPE) is required for this product. The submitted skin sensitization study confirms that the product is not known to be a skin sensitizer.

Detected deviations from protocols are discussed below:

Acute Oral Study (81-1): Individual observations not included. Estimated LD_{50} by sex not provided.

Acute Dermal (81-2): Test material should be applied directly to the skin.

The acute toxicity profile for EPA Reg. No. 211-25 and 211-36 is currently:

Acute Oral	II	Acceptable
Acute Dermal	III	Acceptable
Acute Inhalation	III	Acceptable
Primary Eye	I	Self-Validated
Primary Dermal	I	Self-Validated
Skin Sensitization	non sensitizer	Acceptable

PRECAUTIONARY LABELING

ID #: 000211-00025 PHENO CEN

RESTRICTED USE CLASSIFICATION RECOMMENDED:

Due to eye irritation, dermal irritation, and acute oral toxicity categories.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

SIGNAL WORD: DANGER

PRECAUTIONARY STATEMENTS:

Corrosive. Causes irreversible eye damage or skin burns. May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

NOTE TO PHYSICIAN; Probable mucosal damage may contraindicate the use of gastric lavage.

Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician." The following statements are suggested types of information that may be included, if applicable:

NOTE TO PHYSICIAN (Cont.):

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

PRECAUTIONARY LABELING

ID #: 000211-00036 TRI-CEN GERMICIDAL DETERGENT

RESTRICTED USE CLASSIFICATION RECOMMENDED:

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The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

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- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1, 870.1100)

Product Manager: Adam Heyward, 34
MRID No.: 446504-01

Reviewer: Ann Hanger
Study Completion Date: Dec. 25, 1987
Study No.: 87-1874-21(A)

Testing Facility: Central Solutions, Inc.
Author: Doyle, R.

Quality Assurance (40 CFR §160.12): Included

Test Material: EPA Reg. No. 211-25; Batch No. 108726; clear red liquid
Species: Rats; Albino, Harlan Sprague-Dawley
Age: Young adult
Weight (prefasted): 155-281 g
Source: Harlan Sprague-Dawley, Inc.

Conclusion:

1. LD_{50} **(mg/kg):**
   Males: > 1250 mg/kg
   Females: > 310 mg/kg

2. **The estimated LD_{50} is** > 310 mg/kg
3. **Tox. Category:** II **Classification:** Acceptable

Procedure (Deviations from §81-1): Estimated LD_{50} by sex was not provided. Individual observations were not included.

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
310	0/5	0/5	0/10
620	0/5	4/5	4/10
1250	0/5	5/5	5/10
5000	5/5	5/5	10/10

Observations: At the 310 mg/kg level, observations included mild depression, hunched posture, red liquid stain around mouth and forepaws, yellow liquid stain on nose, gasping gestures, piloerection, urine stains and bloating. One female lost 40 grams over 14 days. At 620 mg/kg, observations included mild depression, gasping gesture, fecal stains, red stain on muzzle and forepaws, hunched posture, enlarged and reddened area of skin around penis, raspy sounding breathing, piloerection, body shakes, frothing at the mouth, and urine stains. One male rat lost 66 grams over 14 days. At 1,250 mg/kg, mild to severe depression, wimpering noises, gasping gestures, hunched postures, urine stains, wet reddish liquid around

mouth, scruffy coats, dried red stains around mouth, piloerection, red stains on muzzle and forepaws, yellow liquid stains around anal area, and eye squinting. At 5,000 mg/kg, severe depression, rasping noises, periodic body spasms, hunched posture, piloerection, squinting eyes, comatose, raspy congested sounding breathing, fecal stains, ataxia.

Gross Necropsy: Gross necropsies at 620 mg/kg included external findings of: urine stains, dried yellow stain around mouth, red stain around nose and forepaws, scruffy coats, blue/green color to skin. Internal findings included: mottled lungs, liver and spleen, dark liver, whitened pancreas, pale and congested kidneys, intestines with yellowing, distention, partially reddened, dak blue/green in color, stomach distended with gas, with small amount of bright yellow material or green food-like material, or small black areas of lining with transparent appearance, stomach smaller in size, moderate PMA, small and pale heart, advanced PMA, little to no body fat. At 1,250 mg/kg, external findings included red staining around uro-genital area, yellow staining around mouth, dried red stains around mouth, red blood-like stains around nose and mouth and on forefeet, red stains on muzzle and forepaws, dried yellow/red stains around anal and stomach area, urine stains, and scruffy hair coat. Internal findings: stomach contained small amount of green food-like material, stomach and small intestines are gassy, stomach small in size and contained clear red liquid with small black matter, or clear yellow liquid, mottled, darkened lungs, congested kidneys, translucent and pale yellow/red small intestines, reddened/yellowed and distended intestines, small spleen, little or no apparent body fat, moderate PMA, mottled liver. At 5,000 mg/kg, external findings of yellow liquid stain around mouth, scruffy coat, dried yellow stains around muzzle, urine stains, dried liquid stain around mouth, and dried red stain around mouth. Internal findings included: pale lungs, darkened and mottled spleen, reddened cardiac region of stomach lining, cloudy light brown, light green, or grey colored liquid in stomach, small amount of green, food-like material in stomach, stomach distended with gas, reddened stomach in some areas, pale and congested kidneys, reddened small intestines, blue/green intestines, mottled liver and moderate PMA.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: Adam Heyward, 34
MRID No.: 443320-06

Reviewer: Ann Hanger
Study Completion Date: July 16, 1997
Study No.: MB 97-5913.02

Testing Facility: MB Research Laboratories, Inc.
Author: Cerven, D.

Quality Assurance (40 CFR §160.12): Included

Test Material: EPA Reg. No. 211-25; Lot 039707; clear light brown liquid
Species: Rabbits; New Zealand White
Age: Young adult
Weight: Males: 2.1-2.3 kg; Females: 2.0-2.2 kg
Source: Ace Animals, Boyertown, PA

Dermal LD_{50} Testing:

Conclusion:

1. **LD_{50} (mg/kg):**
   Males: > 2000 mg/kg
   Females: > 2000 mg/kg
   Combined: > 2000 mg/kg
2. **The estimated LD_{50} is** > 2000 mg/kg
3. **Tox. Category:** III **Classification:** Acceptable

Procedure (Deviations from §81-2): Test material should be applied directly to the skin.

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
2000	0/5	0/5	0/10

Observations: No rabbits died during the study. Instances of diarrhea, few feces and soiling of the anogenital area were noted. Dermal reactions were severe on days 1, 7, and 14 with severe eschar persisting at day 14. Body weight changes were normal in 8/10 animals. One male lost weight during the first week of the study and one female lost weight during the second week.

Gross Necropsy: Necropsy revealed treated skin abnormalities in all animals. Additionally, one female had a soiled anogenital area.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: Adam Heyward, 34
MRID No.: 443320-08

Reviewer: Ann Hanger
Study Completion Date: July 16, 1997
Study No.: MB 97-5913.05

Testing Facility: MB Research Laboratories, Inc.
Author: Cerven, D.

Quality Assurance (40 CFR §160.12): Included

Test Material: EPA Reg. No. 211-25; Lot 039707
Species: Rats; Albino, Wistar
Age: Young adult
Weight: Males: 261-275 g; Females: 226-256 g
Source: Ace Animals, Boyertown, PA

Conclusion:

1. **LC_{50} (mg/L):**
   Males: > 0.53 mg/L
   Females: > 0.53 mg/L
   Combined: > 0.53 mg/L
2. **The estimated LC_{50} is** > 0.53 mg/L
3. **Tox. Category:** III **Classification:** Acceptable

Procedure (Deviations from §81-3): None

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
0.53	0/5	0/5	0/10

Clinical Observations: No rats died during the study. Observations included piloerection, dyspnea, closed eyes, wetness of the nose/mouth and anogenital area, red staining of the nose/mouth area, red appearance to the appendages and coating of the fur with test article were noted early in the observation period. All animals appeared normal from day 3 through day 14. Body weight changes were normal in 8/10 animals. Two females which lost weight by day 7, gained normally by day 14.

Gross Necropsy Findings: No abnormal macroscopic findings were noted.

Chamber Atmosphere		
Grav. Conc.	MMAD	GSD
0.53 mg/L	1.10 μm and 1.04 μm	2.19 μm and 1.85 μm

Other Information: Approximately 89.2-94.6% of particles had an aerodynamic diameter ≤3.3 μm.

Chamber Environment [a]	
Chamber Volume	57 L
Airflow	35 LPM
Temperature	19-20°C
Relative Humidity	54-58%

[a] Whole body

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Adam Heyward, 34
MRID No.: 446504-02

Reviewer: Ann Hanger
Study Completion Date: July 16, 1997
Study No.: MB 97-5913.03

Testing Facility: MB Research Laboratories, Inc.
Author: Kieffer, L.

Quality Assurance (40 CFR §160.12): Included

Test Material: EPA Reg. No. 211-25; Lot 039707
Dosage: 0.5 mL
Species: Rabbits; Albino, New Zealand White
Age: Young adult
Weight: 2.0-2.7 kg
Source: Ace Animals, Boyertown, PA

Conclusion:

1. **Toxicity Category:** I
2. **Classification:** Acceptable

Procedure (Deviations from §81-5): Study terminated at 72 hours without indication of reversibility.

Results: Erythema was severe at all observation intervals. Pale areas were noted on one animal at 30 to 60 minutes following patch removal and moderate to severe eschar, indicative of dermal injury in depth, was observed from 21 through 72 hours. Edema, slight to moderate at 30 to 60 minutes following patch removal, was very slight to slight from 21 through 72 hours.

Special Comments: None

ACUTE TOX ONE-LINERS

1. **REGISTRATION NO.:** 211-25
2. **PC CODE:** 062203 Potassium ortho-benzyl parachlorphenate 8.03%
   064104 Potassium ortho-phenylphenate 6.28%
   064112 Potassium para-tertiary-amylphenate 4.30%
3. **CURRENT DATE:** March 10, 1999
4. **TEST MATERIAL:** PHENO-CEN

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity rat/ Central Solutions, Inc./ 87-1874-21(A)/25-DEC-1987	446504-01	LD_{50} > 310 (combined)	II	A
Acute dermal toxicity rabbit/ MB Research Labs, Inc./ MB 97-5913.02/ 16-JUL-1997	443320-06	LD_{50} > 2000 mg/kg (males, females, combined)	III	A
Acute inhalation toxicity rat/ MB Research Labs, Inc./ MB 97-5913.05/ 16-JUL-1997	443320-08	LC_{50} > 0.53 mg/L (males, females, combined)	III	A
Primary eye irritation rabbit/ MB Research Laboratories/MB 97-5913.04/ 16-JUL-1997	443320-07	Corrosive	I	V
Primary dermal irritation rabbit/ MB Research Labs., Inc./ MB 97-5913.03/ 16-JUL-1997	446504-02	Corrosive	I	V

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**